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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/684,644	10/14/2003	Shalini Sharma	18015-D1	3213
31976	7590	04/08/2004	EXAMINER	
LEWIS J. KREISLER LEGAL DEPARTMENT 930 CLOPPER ROAD GAITHERSBURG, MD 20878			PATEL, SUDHAKER B.	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 04/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/684,644

Applicant(s)

SHARMA ET AL.

Examiner

Sudhaker B. Patel, D.Sc.Tech.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 January 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/15/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' communication paper dated 1/8/04 is acknowledged. Applicants have amended claims 1,2. The claims in this application are the claims 1-13 related to compounds and their biological activity.

First action on merits follows.

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 1/15/04 is being considered by the examiner. A signed copy of the PTO Form 1449 is enclosed with this communication for applicants' record.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim1-13 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: The exact make up of a "Biologically active agent". The claims 1,2 define the term agent as a compound, whereas it is meant as a composition. Also, the claims remain silent for definite and exact meaning of " biological activity". An agent cannot be a single compound. Correction to:" A compound of the Formula I', or Formula I or Formula IB is required.

Claims 1, 2 recite provisos, but do not exactly and definitely spell out the compounds claimed as a novelty. What is excluded in claim 1 is included in claim2. Therefore, it is very difficult to visualize the claimed compounds.

Claims 1, 2 recite X component as: "a group consisting of –NHAC–" What is excluded in the definition of AC. The claim read on to AC as –COCF₃ in addition to –COCH₃ as well. Correction is required.

Claim 3-9,11-13 are included in rejection because they also have the term: agent", and they are presented as dependent on rejected claim(s).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Astle et al (Chemical Abstract DN 124:55567, also cited as WO 9513262 dated 5/1995) as applied to claims above, and further in view of Shoda et al (Chemical Abstract DN 130:281874, also cited as WO 9919291 dated 4/1999).

6. Astles teaches making of a compound with a CAS RN # 170283-05-3 (= Benzene butanoic acid, 2-hydroxy-gama-oxo-4- (3-thienylmethoxy)- methyl ester) and its utility as endothelin inhibitor.
7. The ref.'262 differs from the instant invention by having a heterocycle ring instead of cycloalkyl as claimed herein. Aqstle teaches making of a core: "Heterocycle-CH₂-O-OH substituted phenyl-CO-CH₂-CH₂-CO-Oalkyl". See compound with CASRN # 170283-05-3.
8. The other ref. Shoda teaches making of compounds with CASRN # 222627-31-8/222627-32-9 with a core: "Cycloalkyl-CH₂-O-Substituted Phenyl-CH₂-CH₂-CH₂-COOH.
9. Shoda differs from the instant compounds by having a phenyl group substituted by butyric acid side chain instead of mono-oxobutyric acid as claimed herein.
10. Thus, it would have been obvious to one having ordinary skill in the art at the time of invention to prepare instant compounds by modifying or replacing Heterocycle or Phenyl/ benzene ring with other groups. E.g. cycloalkyl or substituted cycloalkyl ring of Shoda and side chain of Astle, and try out the use/utility as a pharmaceutical by using the conventional chemistry knowledge. The motivation stems from the expectation of making compounds having equal or better pharmaceutical agent.
11. ("Structural relationships may provide the requisite motivation or suggestion to modify one compound to obtain another compound(s)"). For example, one compound may suggest its homologue/isomer, because homology/isomer often have similar properties, and therefore, chemists of ordinary skill would ordinarily contemplate making

them to try to obtain compounds with improved properties, or merely to satisfy their production goals.

12. Claiming of a new use, new function or unknown property, which is inherently present in the prior art, does not necessarily make the claim patentable. In re Best, 562 F. 2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP 2141.02.

13. It has been held that a prior art disclosed compounds is sufficient to render a prima facie case of obviousness as species falling within a genus. See In re SUSI, 440 F 2d 442, 169 USPQ 423, 425 (CCPA 1971), followed by Federal Circuit in Merck & co. V. Biocraft Laboratories, 847 F 2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir.1989).See In re Dillon 16 USPQ 2nd. 1897, 1923 regarding a prima facie case of obviousness of structurally similar compounds disclosed by prior art” regardless to the properties disclosed in the inventor’s application.

Conclusion

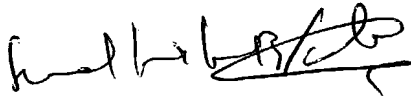
14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhaker B. Patel, D.Sc.Tech. whose telephone number is (571) 272-0671.

The examiner can normally be reached on 6:30 to 5:00 pm (Monday-Thursday). If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Dr. Mukund J. Shah can be reached on (571) 272 0674 or Sr. Examiner Mr. Richard Raymond at (571) 272 0673 or Mr. James O. Wilson at (571) 272-0661.

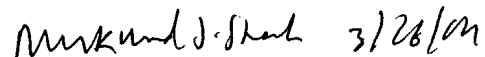
The fax phone numbers for the organization where this application or proceeding is assigned are 703 308 4556 for regular communications and 703 308 4556 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 1235. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sudhaker B. Patel, D.Sc. Tech.
March 26, 2004



MUKUND SHAH
SUPERVISORY PATENT
EXAMINER
ART UNIT 1624/1623